Institution: Keele University

Unit of Assessment: UoA12 Engineering

Title of case study: Advances in treatment of orthopaedic trauma leads to impacts in healthcare and the medical devices industry

Period when the underpinning research was undertaken: 2001 – 2016

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Professor Peter J Ogrodnik	Professor of Biomedical Engineering	2016 – present
Dr Jan Herman Kuiper	Senior Lecturer in Biomechanics	2001 – present
Mr Peter BM Thomas	Consultant Orthopaedic Surgeon; Hon Professor	2001 – 2009 (Senior Lecturer) 2019 – present (Hon. Prof.)
Stephen Dent	Research User Group	n/a

Period when the claimed impact occurred: 1/8/2013 to 31/12/2020

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact (indicative maximum 100 words)

Our work relates to the annual 430 tibial fractures per million population that require surgical intervention: and the annual 1.1 million admissions within UK trauma and orthopaedics. Our research impacted patients, NHS, and other healthcare providers. Exemplar medical devices, that have achieved CE mark and/or Food & Drug Administration (FDA) clearance to market, demonstrate how our research has improved outcomes, enabled patients to return to normal activities sooner, and modified clinical practice. Market reach includes hospitals in 4 continents. We have influenced the profession though books and industrial articles, provided expert opinion for government, and supported ideas to market.

2. Underpinning research (indicative maximum 500 words)

A multi-disciplinary research team, comprising orthopaedic surgeons, nurses, engineers, medical device designers, statisticians, and industrialists from Keele, Robert Jones & Agnes Hunt Orthopaedic Hospital, and Royal Stoke University Hospital have developed computational models and performed patient-focused studies to better understand how long bone fractures heal. A long bone fracture is rarely life threatening, although the outcome could be life changing for the patient. For example, unstable, complex and open lower leg fractures tend to have high complication rates and are often associated with potentially life changing limitations in function and with potential for chronic pain. We have examined how fractures heal, and in the process exposed how a better understanding of fractures can lead to development of new treatments and protocols to enhance healing and lead to improved outcomes. This research has been undertaken in collaboration with end users (clinicians, patients and carers), who informed the research and guided the subsequent development of new medical devices and corresponding surgical techniques.

Exploring how fractures heal
Continuous monitoring of fracture site movement and measurements of fracture stiffness have provided deeper insights into the relationship between mechanical stimulation and fracture healing, as well as exploring fracture healing assessment, and barriers to adoption (3.1, 3.2 & 3.6). This work contributed to a change in the norms associated with the outcomes of tibial fractures and developed new methods for the assessment of fracture healing. We determined that the rate at which a fracture site heals can be explained by a combination of fracture site motion and the remaining gap at the fracture site - a measure of fracture reduction (3.3 & 3.4). This key finding was used as a primary assumption in our computer modelling of long bone fracture healing (3.3), using data gathered on the movement and stiffness of the fracture. Understanding the healing process enabled the development of engineering device solutions for fracture management, and the commercial realisation of these devices: IOS – a single-use disposable external fixation system designed for the treatment of unstable tibial shaft fractures; and STORM (the Staffordshire Orthopaedic Reduction Machine) which is designed to help the orthopaedic surgeon to reduce an unstable lower leg fracture prior to fixation.

Understanding existing treatments
Biomechanical engineering methods were used to assess existing fracture treatments. In addition to work on long bone fractures, studies were performed on other complex fractures, such as transverse fractures of the patella (3.5). This work demonstrated that simple changes from the conventional principles of fixation, could optimise the compression of bone fragments needed for healing, whilst causing fewer failures and improving the stability of the construct. Arguably, pin site infection is one of the major barriers to widespread adoption of external fixation (where pin sites are unavoidable). Investigation of this complication (3.1, 3.2, & 3.6) led to the development of the METAclip, a unique universal clip for all external fixators, designed to create optimal pressure to hold dressings onto the skin.

3. References to the research (indicative maximum of six references)

3.1 Ogrodnik PJ, Moorcroft CI, Thomas PB. 2001. A fracture movement monitoring system to aid in the assessment of fracture healing in humans. Proc Inst Mech Eng H, vol. 215(4), 405-414.

3.2 Moorcroft, C.I., Ogrodnik, P.J., Thomas, P.B. and Wade, R.H., 2001. Mechanical properties of callus in human tibial fractures: a preliminary investigation. *Clinical Biomechanics*, *16*(9), pp.776-782.

3.3 Gomez-Benito MJ, Garcia-Aznar JM, Kuiper JH, Doblaré M. Influence of fracture gap size on the pattern of long bone healing: a computational study. Journal of theoretical biology. 2005 Jul 7;235(1):105-19.

3.4 García-Aznar JM, Kuiper JH, Gómez-Benito MJ, Doblaré M, Richardson JB. Computational simulation of fracture healing: influence of interfragmentary movement on the callus growth. Journal of biomechanics. 2007 Jan 1;40(7):1467-76.

3.5 John J, Wagner WW, Kuiper JH. Tension-band wiring of transverse fractures of patella. The effect of site of wire twists and orientation of stainless steel wire loop: a biomechanical investigation. International orthopaedics. 2007 Oct 1;31(5):703-7.

3.6 McClelland, D., Barlow, D., Moores, T.S., Wynn-Jones, C., Griffiths, D., Ogrodnik, P.J. and Thomas, P.B.M., 2016. Medium-and long-term results of high tibial osteotomy using Garches external fixator and gait analysis for dynamic correction in varus osteoarthritis of the knee. Bone Joint J, 98(5), pp.601-607.

4. Details of the impact (indicative maximum 750 words)

Improving Outcomes through Improved Fracture Reduction
Our research led to the development of an improved treatment pathway and new device to treat fractures – STORM. Used in the operating theatre [5.1, 5.2] STORM helps surgeons to reduce (re-align a fractured bone to its normal anatomical position) and to hold the bone in place whilst selecting the best form of fixation (method for holding in alignment whilst the bone heals). STORM has been independently [5.2, 5.3] demonstrated to shorten operating times, reduce x-ray exposure, improve outcomes, and achieve a significant reduction in the incidence of malunions [5.1, 5.3, 5.4, 5.5]. It is estimated that its use has saved between £1.6M - £3M over the audit period through reduced operating theatre time and costs. In addition, by factoring the average incidence of malunion, an estimated £1-2M in treatment and litigation costs has been saved over the audit period.

Improving the Fracture Management Process
IOS is a novel fracture fixation device which provides external fixation, once reduced, as above [5.2]. Patients treated with IOS (who have previously been treated with other fixation methods) stated a preference over previous treatments [5.5, 5.7]. Further, an audit conducted at the Royal Stoke Hospital demonstrated a significant reduction in healing times (7-8 weeks vs. 16 weeks using the "gold standard" Illizarov ring system) [5.4]. Improved outcomes for patients include: ability to return to normal activity sooner [5.1]; reduction in the risk of malunion; 50% reduction in x-rays over the healing period, and significantly less scaring than alternative fixation methods [5.4]. These improved patient outcomes result in cost savings for healthcare systems and governments through reduction in loss of earnings and productivity, reduction of repeat surgery (malunions normally occur in approximately 10% of patients, a saving of circa £9,000 per patient – or £22.5 M per annum for the UK alone), and reduction in the number of x-rays and clinic time.

Reducing the Incidence of Infection associated with fixation systems
Pin-site infection is a common complication of external fixation and has limited the adoption of external fixation. Our research has led to adoption of a pin-site care pathway in NHS hospital protocols [5.6], and development of a new device, the METAclip. The care pathway has been presented at conferences and training sessions across the UK. The METAclip, has been influenced by both patient and clinical feedback and is sold in the UK and EU [5.7]. Its design allows the clinician to compress the dressing to an optimum level whilst avoiding pressure necrosis [5.2]. There is growing evidence that the use of our care pathway and device has reduced the incidence of pin site irritation and infection [5.2] and hence, a reduction in antibiotic use and associated treatment times [5.2]. It is also being widely used across the whole range of external fixation systems from mono-lateral to ring fixation, and from tibia to pelvis to wrist [5.2].

Impact on health and health practitioners through improved protocols, techniques and training
During the census period over 35,000 fractures and pin sites have been treated with the devices described above [5.7]. The devices, and the techniques they have introduced, are influencing the way practitioners approach the treatment of tibial fractures, in particular [5.1, 5.2, 5.3, 5.4, 5.5 & 5.6]. Our pin site care pathway is now the basis for training most specialist fracture nurses across the UK and on any bone treated with external fixation [5.6]. Further, underpinning interdisciplinary research has generated significant know-how and expertise. Medical Device Design (now in its second edition) is an established textbook for the teaching of medical device design and an essential guide for companies looking to take a new product idea from concept to market. This book has influenced over 38,000 medical devices practitioners [5.8].

Economic and Related Impacts
Our three fracture management devices (sold by METAPHYSIS LLP) support employment and wealth creation in a supply chain that spans 8 other companies in 3 countries [5.7]. The devices have been used and adopted by the NHS and by other healthcare providers worldwide. The company now has products in use in hospitals across 9 countries and 4 continents [5.7]. Sales of STORM and IOS have increased, over the audit period, by 1,200%, with patient interventions by over 200% [5.7]. UK market penetration has also increased: in 2017, METACLIP sales were solely confined to the Royal Stoke hospital, but by 2020 they were in use at major hospitals across the UK, Rep of Ireland and Germany [5.7].

In addition, expertise and know-how from the underpinning research established the foundations of a medical innovation ecosystem in Staffordshire, which has led to the formation of a £2m EU funded programme of SME support, Business Bridge [5.9]. Since 2017, this programme has supported nearly 70 SMEs with healthcare and medical innovations, with 2 products achieving CE Mark in 2020. The programme has spawned a Healthcare Business Network of over 100 members.

5. Sources to corroborate the impact (indicative maximum of 10 references)

5.1 Patient video evidence for STORM and IOS evidencing reduced healing times (*held within Keele's repository*).

5.2 STORM, IOS and METAclip sales literature from METAphysis and Aspen Medical evidencing independent assessments of product performance.

5.3 The use of a tibial reduction device in the treatment of fractures at a district general hospital. Hossain T, Barlow D, Starks I and Barlow T; 19th EFORT Congress 2018.

5.4 A practical, quantitative, fracture healing endpoint assessment criterion for tibial fractures treated with external fixation; Ogrodnik P, Thomas PBM; Proc IMechE Part H: J Engineering in Medicine2019, Vol. 233(5) 497–505; https://journals.sagepub.com/doi/abs/10.1177/0954411919835453

5.5 Testimonial from Quershi, A.A, FRCS, University Hospital Southampton.

5.6 Northern Care Alliance, Pin site care guidelines issued 9 Oct 2019. https://www.srft.nhs.uk/EasysiteWeb/getresource.axd?AssetID=33132&type=full&servicetype=Inline

5.7 Testimonial from CEO of METAPHYSIS and PPIE market surveillance **(Confidential)**

5.8 Testimonial from Elsevier for downloads of Medical Device Design, 1st and 2nd Editions. https://www.elsevier.com/books/medical-device-design/ogrodnik/978-0-12-814962-1

5.9 Testimonial from EU funded programme, Business Bridge supporting medical device innovation.